



VIA ECF

March 9, 2020

Re: MDL No. 2875

Dear Judge Kugler and Judge Schneider:

We write to provide Defendants' proposal regarding how this MDL should be "managed and tried, including Fed. R. Civ. P. 12(b), class certification and Daubert issues." ECF 388.

This MDL concerns three drugs, valsartan, losartan, and irbesartan, each with its own unique manufacturing process and regulatory profile. The allegations of nitrosamine impurities in each drug differ. Plaintiffs still have not filed master complaints as to irbesartan or losartan.

Currently, as to valsartan, the MDL is comprised of approximately 260 personal injury, consumer class action, third-party payor class action, and medical monitoring claims. The plaintiffs in these actions have consolidated their claims into three Valsartan Master Complaints: personal injury, economic loss, and medical monitoring.

As set forth in the schedule attached as Exhibit A, Defendants propose the following sequence of key pretrial events pursuant to Valsartan Master Complaints: (1) an omnibus Rule 12(b) motion addressing the economic loss claims; (2) an omnibus class certification motion on behalf of all consumers; (3) an omnibus *Daubert* proceeding on the issue of general causation; (4) Rule 56 motions; and (5) a trial involving claims, classes, and Defendants, as narrowed by the Rule 12, class certification, *Daubert*, and summary judgment rulings. This efficiency-enhancing proposal is grounded in decades of MDL management and Rule 23 experience.

It is our understanding, based on the February 26 conference, that Plaintiffs will propose filing, in succession 60 to 90 days apart, at least four motions for class certification. Each motion would seek certification of a class of consumers who purchased valsartan containing API from one API manufacturer and all downstream Defendants, which Plaintiffs refer to as an "API pyramid." Plaintiffs also propose successive Rule 12(b) motions in conjunction with each class certification motion. Should a class be certified, Plaintiffs propose a trial of the warranty claims asserted against that specific API pyramid. Plaintiffs' proposal is novel and unmanageable. Indeed, we have found no other instance of successive class certification motions in the vast precedent under Rule 23.

I. Omnibus Rule 12(b) and Class Certification Motions Are Grounded in Decades of MDL and Class Action Precedent

The underlying purpose of both MDLs and class actions is to facilitate the fair and efficient resolution of litigation. *See Manual for Complex Litigation* § 20.131. The central purpose of 28 U.S.C. § 1407 is to "eliminate duplication in discovery, avoid conflicting rulings and schedules, reduce costs, and save time and effort of the parties...." *Gelboim v. Bank of Am. Corp.*, 135 S. Ct. 897, 903 (2015). "Indeed, one of the primary efficiencies" of MDLs is "the resolution on a common basis of certain dispositive issues that would either narrow or eliminate entirely the aggregate mass of asserted claims." Douglas G. Smith, *Resolution of Commons Questions in MDL*

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Proceedings, 66 U. Kan. L. Rev. 219, 225 (2017).¹ Combined, Rule 23 and § 1407 provide courts with powerful tools to drive related actions toward resolution. *See Managing Related Proposed Class Actions in Multidistrict Litigation* at 1,4,9.²

For a variety of reasons, an omnibus Rule 12(b) motion, which would include any defendant-specific issues, followed by an omnibus class certification motion would enhance the efficiency of these proceedings. Rule 12(b) will narrow the class or sub-classes and claims that might be subject to certification under Rule 23. Then, class certification itself will likely further narrow the case, as a “class certification ruling may eliminate unnecessary pretrial practice and expense. Sometimes certifiability of a class is the key legal issue that will best advance the litigation.” *Managing Related Proposed Class Actions in Multidistrict Litigation* at 8. Through an omnibus motion, the transferee Court can satisfy the goals of Rule 23 and § 1407 by moving the entire case towards resolution.³

A. An Omnibus Rule 12(b) Motion Should Precede Class Certification

While the Court has stayed all motions for the time being, precedent dictates that Rule 12(b) motions should precede class certification. “Most courts agree, and Rule 23(c)(1)(A) reflects, that such precertification rulings on threshold dispositive motions are proper.” *Manual for Complex Litigation* § 21.133 at 253. This is because “[e]fficiency and economy are strong reasons for a court to resolve” preliminary legal issues. *Id.* In fact, the *Manual for Complex Litigation* recommends the Court “direct counsel to raise such challenges before filing motions to certify,” as “[e]arly resolution of these questions may avoid expense for the parties and burden for the court and may minimize use of the class action process....” *Id.* Even if not dispositive, rulings on the following Rule 12(b) questions, for example, should materially affect class certification briefing:

- Does the court have personal jurisdiction over each Defendant and each claim?
- Do plaintiffs who did not suffer any physical injury from taking valsartan have standing?
- Do plaintiffs who pay the same co-pay for similar drugs have standing?
- Does the FDCA preempt the allegation that valsartan was “worthless”?
- Does the Drug Supply Chain Security Act preempt certain claims?
- Does the FDA’s primary jurisdiction preclude courts from deciding Plaintiffs’ adulteration, misbranding, bioequivalence, and/or “new drug” assertions?
- Does FDA-approved labeling preempt liability?
- Do innocent seller statutes preclude claims against downstream Defendants?
- Which states recognize warranty actions for pharmaceutical products?
- Did manufacturers warrant impurity-free valsartan?

¹ A copy of this article is attached as Exhibit B.

² Available at <https://www.fjc.gov/content/331992/managing-related-proposed-class-actions-mu>ltidistrict-litigation.

³ Furthermore, resolving preliminary legal issues and class certification is one of the transferee court’s most vital early tasks. *Managing Multidistrict Litigation in Products Liability Cases: A Pocket Guide for Transferee Judges* at 17, available at <https://www.fjc.gov/content/managing-multidistrict-litigation-products-liability-cases-pocket-guide-transferee-judges-0>.

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B. An Omnibus Class Certification Motion Should be Required

It is widely accepted that motions for class certification in consolidated cases involving multiple defendants and claims should be asserted against all defendants in a single motion, typically based on allegations contained in a master complaint. *See, e.g., Norwood v. Raytheon Co.*, 237 F.R.D. 581, 584-85 (W.D. Tex. 2006); *Bentley v. Honeywell Intern., Inc.*, 223 F.R.D. 471, 474-75 (S.D. Ohio 2004); *In re Phenylpropanolamine (PPA) Prod. Liab. Litig.*, 214 F.R.D. 614, 615 (W.D. Wash. 2003); *Mejdreck v. Lockformer Co.*, No. 01-6107, 2002 WL 1838141, at *1-2, 10 (N.D. Ill. Aug. 12, 2002); *In re Stucco Litig.*, 175 F.R.D. 210, 211 (E.D. N.C. 1997); *In re Orthopedic Bone Screw Prod. Liab. Litig.*, No. 93-7074, 1995 WL 273597, at *1 (E.D. Pa. Feb. 22, 1995). Indeed, “omnibus motions” are a “standard way in which...issues are resolved” in MDLs, *see Smith*, 66 U. Kan. L. Rev. at 229, and class certification in an MDL is no different. *See, e.g., In re FCA US LLC Monostable Electronic Gearshift Litig.*, No. 16-2744, 2019 WL 6696110, *4-12, *16 (E.D. Mich. 2019); *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 65 n.1, 75-96 (D. Mass. 2005); *In re Vioxx Prods. Liab. Litig.*, 239 F.R.D. 450, 459 (E.D. La. 2006).

As in virtually every other consolidated class action, the putative class representatives should be required to seek certification in an omnibus motion that proposes a class or subclasses based on the claims asserted in the Economic Loss Master Complaint and articulates a manageable plan for trial of those claims. *See Grandalski v. Quest Diagnostics Inc.*, 767 F.3d 175, 183 (3d Cir. 2014) (holding that plaintiffs bear burden of demonstrating a workable trial proposal for nationwide class); *Chin v. Chrysler Corp.*, 182 F.R.D. 448, 459 (D.N.J. 1998) (“Plaintiffs... have the burden of designing a workable plan for trial...prior to class certification.”). The Economic Loss Master Complaint asserts class action claims on behalf of 24 putative class representatives and similarly situated consumers, all of whom allegedly comprise a nationwide class and/or subclasses for each of the 50 states, against fifty-plus Defendants at various levels of the supply chain. *See ECF 121*, ¶¶ 413–15. And the class action allegations in the Economic Loss Master Complaint raise questions that are applicable to all of the putative class members, regardless of which API manufacturer’s valsartan they claim to have ingested, that would determine whether any of them could be included in a certifiable class or sub-class, such as:

- When did the consumer take valsartan: before, during, or after the recall?
- Did the consumer receive, or could the consumer have received, a refund?
- Did the consumer ingest valsartan containing unsafe levels of nitrosamines?
- Would the consumer’s doctor have prescribed an alternative drug?
- Can Plaintiffs demonstrate a class-wide damages model?

The consistency of the above opinions can be explained by simple rules of efficiency and judicial economy. An omnibus class certification motion provides flexibility for structuring different trial plans without sacrificing the preclusive benefits of a comprehensive certification decision. Any Defendant-specific issues related to certification could still be addressed in this context. Further, because the certification decision would bind all parties, rather than only one so-called “API pyramid,” summary judgment, *Daubert* rulings on scientific issues, and issue-specific trials would have similarly broad effects. But should certification be granted, Plaintiffs could still seek to sever a specific subclass or issue class for a discrete trial. An omnibus motion would thus increase efficiency while maximizing flexibility.

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C. Class Certification Must Occur Before any Liability Determination

Federal courts have uniformly adopted the rule against one-way intervention, which precludes a liability determination on an individual plaintiff's claims before a ruling on class certification under Rule 23(b)(3). *See Am. Pipe & Const. Co. v. Utah*, 414 U.S. 538, 547 (1974); *London v. Wal-Mart Stores, Inc.*, 340 F.3d 1246, 1252–53 (11th Cir. 2003) (“Rule 23(c)(2)’s requirement that, in opt-out class actions, notice be given to all class members as soon as practicable was intended by Congress to prevent one-way intervention.”); *Schwarzchild v. Tse*, 69 F.3d 293, 296 (9th Cir. 1995) (Rule 23 “clearly contemplates that the notice requirement will be met *before* the parties are aware of the district court’s judgment on the merits.”); *Premier Elec. Const. Co. v. Nat'l Elec. Contractors Ass'n, Inc.*, 814 F.2d 358, 362 (7th Cir. 1987); *Katz v. Carte Blanche Corp.*, 496 F.2d 747, 759 (3d Cir. 1974); *Koehler v. USAA Ca. Ins. Co.*, No. 19-715, 2019 WL 4447623, at *7 (E.D. Pa. Sept. 16, 2019); *Northwestern Mut. Life Ins. Co. v. Valeant Pharm. Int'l Inc.*, No. 18-15286, 2019 WL 4278929, at *11–*12 (D.N.J. Sept. 10, 2019). As the Seventh Circuit explained:

The rule exists because it is unfair to allow members of a class to benefit from a favorable judgment without subjecting themselves to the binding effect of an unfavorable one. [...] If an individual plaintiff got an unfavorable ruling on the merits prior to class certification, class members are incentivized to opt out of the class.... Allowing class members to decide whether or not to be bound by a judgment depending on whether it is favorable or unfavorable is ‘strikingly unfair’ to the defendant.

Costello v. BeavEx, Inc., 810 F.3d 1045, 1058 (7th Cir. 2016) (internal citation/quotation omitted).

II. Successive Class Certification Motions Would Be Unprecedented and Unmanageable

The rigorous nature of class certification proceedings makes the use of multiple, successive motions unmanageable. The party seeking class certification must establish each element of Rule 23 by a preponderance of the evidence, which will require extensive briefing and complicated *Daubert* issues. *See In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 307, 316 (3d Cir. 2008); *see also Hohider v. United Parcel Serv., Inc.*, 574 F.3d 169, 197 (3d Cir. 2009) (explaining the “rigorous analysis” under *Hydrogen*). Courts’ “broad discretion to control proceedings” does “not soften the rule: a class may not be certified without a finding that each Rule 23 requirement is met.” *Hydrogen*, 552 F.3d at 310. The replication of this process four times will spin the litigation out of control.

In addition, a decision to certify one “API pyramid” class would not bind the remaining pyramids. *See In re Gen. Motors Corp. Pick-Up Truck Fuel Tank Prods. Liab. Litig.*, 134 F.3d 133, 146 (3d Cir. 1998). Thus, the first certification decision would not lessen the burden of deciding subsequent Rule 23 motions as to the other API pyramids. Replicating these fact intensive questions over a series of motions invites classes with inconsistent factual determinations. This would further frustrate the efficient resolution of this MDL. *In re Rhone-Poulenc Rorer, Inc.*, 51 F.3d 1293, 1298 (7th Cir. 1995); *see also Hydrogen*, 552 F.3d at 310.

Furthermore, staging four successive motions by 60 to 90 days (or more) would cause serious delay. Plaintiffs’ motions alone would take up to 270 days to file. This does not account

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for Defendants' responses, Plaintiffs' replies, or *Daubert* hearings on damages modeling as to each separate motion, not to mention the four inevitable appeals. And should the Court grant certification for any of these motions, there would be the additional delay involved with drafting, approving, and mailing a class notice, and providing a sufficient opt-out period for any and classes certified, and before a trial as to any API pyramid may be conducted. Even simply finalizing four notices that comply with Rule 23(c)(2)(B) will be difficult. Many individuals have consumed API from multiple manufacturers; four separate notices tied to four API manufacturers will undoubtedly confuse consumers who may be members of multiple classes.

III. Plaintiffs' Proposal Would Effectively Violate the Rule Against One-way Intervention

Successive motions would present an impermissible, lose-lose proposition for Defendants. *See, e.g., Katz*, 496 F.2d at 762. Unless the Court decides all four class certification motions before hearing any substantive issue on the merits, later-briefing class members will "stand on the sidelines" and observe the outcome before their opt-out period. *Nw. Mutual*, 2019 WL 4278929, at *12; *see also Premier Elec.*, 814 F.2d at 367. "If the first case proceeds well, the bystander[s] will take the benefit, and if not [they] will try again. The benefits of presenting common claims in a single forum will be lost." *Id.* Even though rulings on one "API pyramid" would not bind later pyramids, plaintiffs would be able to evaluate how their claims will likely fare before having to "cast [their] lot[.]" *Id.* at 362. Defendants would enjoy no such benefit; they cannot simply opt out after a bad result. This is precisely the type of unfair situation that the rule against one-way intervention prevents.

IV. Early *Daubert* Proceedings on General Causation Would Streamline the Litigation

In MDLs involving allegedly defective drugs, one "primary common issue[]" is causation. *Smith*, 66 U. Kan. L. Rev at 232. "Numerous courts" have used "*Daubert* proceedings in order to narrow or even resolve entirely complex multidistrict litigation." *Id.*; *see also id.* at 232–44 (collecting numerous example MDLs). That approach is warranted here, where the issue of general causation is applicable to all of the personal injury, economic loss, and medical monitoring claims asserted. Thus, deciding general causation issues could significantly streamline this litigation. For example, as in the Lipitor MDL, a *Daubert* decision could limit all three types of claims to valsartan above a specific dose or containing nitrosamines above a particular concentration. *See id.* at 237–39. Or like the Heparin MDL, *Daubert* rulings could narrow the claims to individuals without certain preconditions or other alternative causes. *See id.* at 233–36.

V. Summary Judgment and Trial

The manuals, guides, articles, and cases cited herein dictate that the scope of a trial in this MDL should be based on the Rule 12, class certification, and *Daubert* rulings, as well as any summary judgment rulings pertaining to issues not resolved by earlier rulings.

Respectfully submitted,

/s/ Seth A. Goldberg

Seth A. Goldberg

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cc: Adam Slater, Esq. (*via email, for distribution to Plaintiffs' Counsel*)
Jessica Priselac, Esq. (*via email, for distribution to Defendants' Counsel*)
Sarah Johnston, Esq. (*via email*)
Lori G. Cohen, Esq. (*via email*)
Clem C. Trischler, Esq. (*via email*)